UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,469	10/20/2003	Patrice Debregeas	065691-0339	4165

22428 7590 02/02/2009

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
BASQUILL, SEAN M	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
02/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/689,469	DEBREGEAS ET AL.	
	Examiner	Art Unit	
	Sean Basquill	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-11 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-11 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *23 December 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 December 2008 has been entered.

Claim Objections

2. Claim 8 is objected to because of the following informalities: the phrase "...contains comprises a copolymer..." is nonsensical, but apparently a typographic error wherein "contains" was not appropriately removed or indicated as deleted text. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 2, 5-10, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,056,949 ("Menzi"), in view of U.S. Patent 6,030,621 ("De Long") and U.S. Patent 4,954,350 ("Jones").

With regard to amended Claim 1, the examiner has construed the instant claim as reciting a product-by-process, where patentability is defined not by the process steps but by the product obtained. MPEP § 2113. Claim 1, and those dependent therefrom, therefore describe a plant substance granule comprising a single neutral core between 200-1600 microns coated with a layer containing a dry plant extract combined with polyvinylpyrrolidone.

Jones describes the use of pharmaceutically acceptable binders such as PVP as part of a carrier to apply active pharmaceuticals to inert core granules. (C.3, L.50-54). Jones additionally describes coating an active agent containing core with a mixture of polymers or copolymers of methacrylic acid and ethyl cellulose to provide controlled-release pharmaceutical formulations. (C.3, L.1-8). Jones indicates that generally the coated units comprise between 5-25% of the active agent. (C.4, L.27-28). Jones also teaches forming coated units using other therapeutic agents for either immediate or controlled release. (C.4, L.36-43). Jones does not describe using extracts of *ginko biloba* as a pharmaceutically active ingredient, nor is the use of inert sugar or sugar alcohol cores to receive the active agent coating used.

De Long describes the preparation of phytopharmaceutical extracts of *ginko biloba* by various means to achieve a dry extract. (C.2, L.35 – C.6, L.22) These extracts are then

incorporated, along with pharmaceutically acceptable carriers (C.10, L.33-54), into pharmaceutical formulations such as granules for oral administration. (C.10, L.21-25).

Menzi describes an inert pharmaceutical core material of between 0.02-3.0 mm comprising sugars or sugar alcohols. (C.2, L.6-15). Menzi additionally describes these cores as capable of being coated with additional materials suitable for coating sugar granules and which form a protective skin or film on the core. (C.2, L.40-48).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to combine the phytopharmaceutical extracts of De Long with the formulations of Jones to arrive at pharmaceutical granules containing ginko biloba extracts. Moreover, one having ordinary skill in the art would have used inert cores such as those described by Menzi to arrive at the instant invention. One having ordinary skill in the art would have been motivated to do this because Jones specifically describes formulating granules using inert cores, and Menzi describes the physical parameters of such cores. One having ordinary skill in the art would have recognized that the granules of Jones could be modified to carry any pharmaceutically active agent, not simply the acrivastine or exemplary "other therapeutic agents" specifically described. *KSR v. Teleflex*, 127 S.Ct. 1727, 1742 (2007) (a person of ordinary skill is…a person of ordinary creativity, not an automaton). One having ordinary skill in the art would have been motivated to use the granules described by Menzi in the pharmaceutical composition because both Jones and De Long specifically describe formulating granules, and Jones specifies using inert cores such as a non-pareil.

4. Claims 3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones as modified by De Long and Menzi as applied to claim1 above, and further in view of U.S. Patent 6,228,395 ("DeBregeas").

Jones as modified by De Long and Menzi, above, describe inert pharmaceutical cores coated with ginko biloba extract using PVP as a pharmaceutically acceptable binder. Jones as modified by De Long and Menzi do not specify using a core comprising starch/sucrose in a 20/80 mass ratio.

DeBregeas indicates that commonly used pharmaceutically acceptable granular supports for pharmaceutical formulations consist of grains comprising sucrose and starch in "a weight ratio in the region of 75/25, such as those described under the name 'sugar spheres' [in the Handbook of Pharmaceutical Excipients]." (C.3, L.9-15). DeBregeas also describes coating the cores using "any pharmaceutically acceptable binder useful for coating granular supports such as PVP...or hydroxypropylmethylcellulose." (C.3, L.25-31).

Where the general conditions of a claim are known via the prior art, such as sugar/starch mass ratio "in the region of" 75/25, it is not inventive to discover optimum or workable ranges, such as the sugar/starch mass ratio of 80/20 as claimed in the instant application by the routine experimentation of one having ordinary skill in the art, absent evidence presented indicating the claimed range is critical. MPEP § 2144.05(II)(A).

It would have been prima facie obvious to one having ordinary skill in the art at the time of the instant invention to use the inert cores described by DeBregas in the invention of Jones as modified by De Long and Menzi to arrive at inert pharmaceutical cores coated with ginko biloba extract using PVP, or a combination of PVP and hydroxypropylmethylcellulose as a

pharmaceutically acceptable binder where the cores comprise sucrose and starch in a weight ratio of 80/20. One having ordinary skill in the art would have been motivated to do so because of the art-recognized equivalence of the DeBregeas, Jones, and Menzi cores, and the art-recognized equivalence of PVP and hydroxypropylmethylcellulose binders as disclosed by DeBregeas.

Conclusion

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill
Art Unit 1612

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642